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EXAMIN
MEHTA, ASH

ART UNIT
1638

DATE MAILED: 01/16/2004

Please find below and/or attached an Office communication concerning this application or proceedin

Office Action Summary	Application No.	Applicant(s)	
	10/057,315	FLOYD, MICHAEL L.	
	Examiner	Art Unit	
	Ashwin Mehta	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-25 and 27-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,5,7-10,12,13,15 and 17-23* is/are allowed.

6)☒ Claim(s) *2,3,6,11,14,16,24,25 and 27-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. The objection to claim 26 is withdrawn, in light of its cancellation.

3. The rejection of claims 15 and 17-20 under 35 U.S.C. 112, 2nd paragraph, is withdrawn in light of the claim amendments.

Claim Rejections - 35 USC § 112

4. Claims 2, 3, 6, 11, 14, 16, and 27-30 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record stated in the Office action mailed July 9, 2003. Applicant traverses the rejection in the paper filed October 9, 2003. Applicant's arguments have been fully considered but were not found persuasive.

Regarding claim 2: Applicant argues that claims must be given their plain meaning and limitations must not be read into a claim (response, paragraph bridging pages 7-8). However, the claim is not being interpreted based on only a single limitation. Further, a claim must be definite for all of its limitations, not just a subset. Applicant provides the definition for "population" from the Meriam-Webster on-line dictionary (Exhibit A). One definition indicates that a

population is "the total of individuals occupying an area or making up a whole." This does not limit every individual to be identical, or different. Another definition states, "a body of persons or individuals having a quality or characteristic in common." However, as applied to the instant claim, the quality or characteristic in common can be that every individual is a corn seed, but every seed does not have to be of variety I501150. It remains unclear whether Applicant intends for the population of claim 2 to consist of seed of corn variety I501150, or if the population can comprise other varieties of seed. It is suggested that the recitation, --consisting-- be inserted in line 1 after "seed", if Applicant intends the population to consist only of I501150 seed. If Applicant intends for the population to comprise other varieties of corn seed, it is suggested that the recitation, --comprising seed-- be inserted in line 1 after "seed".

Regarding claim 3: Applicant argues that while claim 2 is directed to a population of seed of corn variety I501150, it is not necessary that the population be essentially homogeneous. Applicant provides the definition for "population" from the Meriam-Webster on-line dictionary (Exhibit A), and argues that the relevant definition is "a body of persons or individuals having a quality or characteristic in common." Applicant also provides the definition for "homogeneous" (Exhibit B), which is "of uniform structure or composition throughout", and argues that a collection of seed may at one time have a quality or characteristic in common, e.g. be of variety I501150, yet not be of uniform structure or composition, for example size or shape (response, paragraph bridging pages 8-9).

However, the rejection never mentioned that the claim is indefinite because the individual I501150 plants of the population vary in size and shape, while possessing the identical genome. In the argument, Applicant appears to be indicating that "essentially homogeneous" refers to the

non-uniform nature, for example shape and size, of a single variety of seed. However, this is not consistent with the discussion of "essentially homogeneous population of inbred seed" on page 5, lines 15-21, which indicates that such a population consists essentially of the particular inbred seed, are generally free from substantial numbers of other seed, and that the inbred seed may form less than 100% of such populations. Applicant's current argument is also inconsistent with the paper submitted April 14, 2003, in which Applicant argued that a population may potentially include a small amount of other seed (page 7, 2nd full paragraph). Note that if claim 2 is amended as suggested above to indicate that the population of seed comprises seed of corn variety I501150, the rejection to claim 3 would also be overcome.

Regarding claims 6 and 11: Applicant provides the definition for "accordance" that appears in the on-line version of the Meriam-Webster Dictionary, one of which is "agreement, conformity" (Exhibit C). Applicant argues that the term therefore has a well known meaning in the art and its use in the claim is not indefinite (response, paragraph bridging pages 9-10).

It remains unclear whether the claimed inbred plant cell or plant has the SSR profile or the genetic isozyme typing profile of Tables 5 and 6. It is not clear, for example, what is meant by an SSR profile that is in conformity with the profile shown in Table 5. Is the SSR profile the same, or is it not the same, as that shown in Table 5? Would an SSR profile that generally follows the trend of the profile of Table 5, but which differs at one or a few loci, be considered in "conformity" or "in accordance" with the profile of Table 5? It is not clear what is meant by a marker profile that "agrees" with another marker profile. Are they the same or not? If the profiles are not exactly the same, then it is not clear what the differences are. If Applicants intend for the claimed inbred plant cell or plant to have the same profiles as those shown in

Tables 5 and 6 for corn plant I501150, it is suggested that part (a) of claims 6 and 11 be replaced with --the SSR profile for corn plant I501150 shown in Table 5; and--, and that part (b) of the claims be replaced with --the isozyme typing profile for corn plant I501150 shown in Table 6--.

Regarding claim 14: Applicant argues that a population need not be essentially homogeneous (response, page 9, 1st full paragraph). However, the claim clearly states, "An essentially homogeneous population of corn plants..."

Applicant again argues that a population of plants grown from I501150 seed could vary in size or other characteristics due to environmental or other conditions, but still be population produced by growing I501150 seed (response, page 9, 1st full paragraph). However, again, Applicant's interpretation of "essentially homogeneous population" differs from that provided on page 5, lines 15-21 of the specification, which explains how other varieties of seed may be in such populations. Applicant's current argument is also contradictory to Applicant's previous argument that the population can comprise other plants (response filed April 19, 2003, page 8, 2nd full paragraph). The population of claim 14 is essentially homogeneous, and can comprise other varieties of seed. Yet, the claim indicates that plants of the population are produced by growing only seed of variety I501150. It is not clear, if the only seed that is to be grown is I501150, how the population can be "essentially homogenous" and comprise other types of plants.

Regarding claims 16-27: Applicant argues that claim 16 adds a gene conferring male sterility, while claim 27 adds a single locus conversion, to the parent claim. Applicant argues that the claims contain a reference to the parent claim, contain a further limitation of the subject matter claimed in the main claim, and incorporate all elements of the claim from which they

depend. Applicant argues that how the plants acquire the added elements is irrelevant to the scope or definiteness of the claims, as they are product claims, not process or product by process claims (response, page 10, last paragraph).

However, the claims do not incorporate all elements of their parent claims. The plants of the parent claims are capable of expressing, or have, all of the morphological and physiological traits of corn plant I501150, which is male fertile. The plant of claim 16, however, is not male fertile. Therefore, claim 16 does not incorporate all elements of the claim from which it depends. As the plant of claim 15 is male fertile, it is contradictory to say that claim 16 incorporates all elements of claim 15, yet is directed to a plant that is not male fertile. The single locus conversion of the plant of claim 27 does not have to be a gene that confers male sterility. However, as the locus may encode any trait, and can affect the plant of parent claim 5 in any manner, the plant of claim 27 does not have to have all of the traits expressed by the plant of claim 5. The plant of claim 27 then would not have all of the limitations of the plant of claim 5. Further, the specification indicates that the backcrossing protocol that is used in introducing a single locus conversion into a plant, can result in a single locus being modified or substituted in the recurrent inbred (page 29, lines 11-15). The plant of claim 27, then, does not have to possess all of the limitations of the plant of the parent claim.

Regarding claim 28: Applicant notes that the single locus may or may not have been directly inserted into the genome of the claimed plant, but argues that this does not render the claim indefinite. Applicant argues that the single locus need not have been directly inserted into the genome of I501150, and that loci that are stably inserted into a corn genome are also stably inherited (response, page 11, 2nd full paragraph).

However, it remains unclear what other genomes are encompassed by "a corn genome," and how does it relate to the plant of claim 28? If the single locus is inserted into another corn genome, the claim does not indicate how it came to be within corn plant I501150.

Regarding claim 30: Applicant argues that those of skill in the art understand all the terms and there is no prohibition upon the use of relative terms. Applicant argues that the terms must be read in the context of the claim in which they are found, that the subject claim recites a single locus that confers the traits of yield enhancement, improved nutritional quality, and enhanced yield stability, and that it is understood that the enhancement of yield or yield stability and improvement in nutritional quality is relative to a plant lacking the single locus. The metes and bounds of the claim would thus be fully understood by one of skill in the art (response, paragraph bridging pages 11-12).

However, relative terms cannot be used if the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Here, the specification does not provide any such standard. What one may consider an enhancement or improvement over a plant lacking the single locus, may not be considered so by another, in the absence of a defined standard that must be met. Further, what nutritional qualities are contemplated, and how are they improved?

5. Claims 24, 25, and 27-31 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed July 9, 2003. Applicant traverses the rejection in the paper filed October 9, 2003. Applicant's arguments have been fully considered but were not found persuasive for claims 24, 25, and 27-31. The rejection has been withdrawn from claims 2, 3, and 14 upon further consideration. Claims 4 and 26 are cancelled.

Applicant argues that the hybrid seeds and plants of claims 24-25 are described because they have I501150 as a parent and therefore contain a copy of the same genome as corn plant I501150, that the hybrids have inherited half of their genetic material from I501150. Applicant also argues that the entire genetic contribution of corn plant I501150 is described by way of deposit of seed of I501150 with the ATCC, and believes that this represents a description of concrete and identifiable structural characteristics defining the claimed hybrid plants and distinguishes them from other plants. In support, Applicant cites the decision of *Enzo Biochem, Inc. v. Gen-Probe Inc.*, for holding that a biological deposit constitutes a written description of the deposit material (response, paragraph bridging pages 13-14).

However, that all hybrids will inherit half of their alleles from I501150 does not provide any information concerning the morphological and physiological characteristics that will be expressed by the claimed hybrids. The specification does not correlate any genes of I501150 with any of the traits that it expresses. Further, the claimed hybrids will inherit one allele for every gene from the other, unidentified and undescribed parent plant. The specification does not describe how those alleles inherited from I501150, or how the products of those alleles, will be affected by or interact with the alleles or their products inherited from the other parent. The

expressed gene products will depend on the combination of the two alleles from each parent at each locus, whether the allele is dominant or recessive, and on the epigenetic effects of other genes. The fact that any hybrid plant will inherit half of its alleles from I501150 then does not provide sufficient description of the morphological and physiological characteristics expressed by the claimed hybrid plants. In the patent application considered in *Enzo Biochem Inc. v. Gen-Probe Inc.*, the deposited material corresponded exactly to the claimed product, and a function was correlated with the structure of the product that was deposited. Here, the deposited inbred does not correspond exactly to the claimed hybrid. In addition, the functions of the claimed hybrid plants have not been correlated to the half of their genetic material originating from the deposited I501150 seed. The function of the plant grown from an I501150 seed is correlated with the structure of its entire genome, not just one half. The function of the claimed hybrid plants grown from the claimed hybrid seeds is correlated with the structures of their entire genomes, not just the alleles inherited from I501150. Further, half of the alleles of the hybrid are inherited from the other parent, and are not described by the deposited I501150 seed. Therefore, the claimed hybrids do not have the same, complete genetic structure and function as that possessed by the deposited I501150 seed.

Applicant continues, citing the decision of *The Regents of the University of California v. Eli Lilly and Co.*, for noting that a name alone does not satisfy written description if structural features commonly possessed by members of the genus are not defined. Applicant argues that here, all of the members of the claimed genus of hybrids having I501150 as one parent share the identical feature of having the genetic complement of I501150 (response, paragraph bridging page 14, 1st full paragraph). However, in *Eli Lilly*, the members of the genus shared a common

function. In the instant application, the specification does not describe the function (i.e., morphological and physiological traits) of the claimed hybrids, and does not correlate the function of the hybrids with the structure of the genetic complement of I501150. Furthermore, the genetic complement of the other unknown parent has not been described, and hence Applicant has not provided a written description of the multitude of possible hybrid corn seeds and plants that would result from crossing the deposited inbred I501150 with any and all other inbred or hybrid corn plants.

Applicant argues that the claimed F1 hybrid plants having I501150 as one parent will share the same genetic complement from I501150, and are readily identifiable by the genetic marker analysis in Tables 5 and 7. Applicant argues that hybrid corn plant 9903904 has the SSR genetic marker profile of I501150 and includes the genetic markers from the second parent plant, and that this will be true for any other hybrid plant having I501150 as one parent, save for "an occasional difference at a locus due to spontaneous genetic rearrangements" (response, paragraph bridging pages 14-15). However, while all of the claimed hybrids will inherit the SSR marker profile of I501150, they will not inherit the same genetic markers from the other parent as did hybrid 9903904, because they will have different parents, having different markers. The SSR marker profiles of the other parents are not described. Further, the description of corn plant 9903904 does not describe the morphological and physiological traits of all other corn plants that can be produced by crossing I501150 to any other corn plant. One skilled in the art cannot identify the morphological and physiological characteristics of corn plant 9903904 that will be expressed by all other members of the genus, nor can one identify the characteristics that will be different. Further, while hybrid 9903904 has inherited the SSR marker profile of I501150, the

specification does not describe the traits that are correlated with these markers. The traits expressed by 9903904 are not solely due to the presence of the alleles associated with the SSR markers inherited from the I501150 genome, or the genetic contribution of I501150, as discussed above.

Applicant continues, arguing that the second plant that is used to make the claimed hybrids is irrelevant, as any second plant capable of reproduction may be used to make the hybrid. Applicant argues that the claims cannot be said to lack written description for the second genetic complement, particularly given that hundreds or even thousands of different inbred corn lines were well known to those of skill in the art. Applicant points to the more than 195 patents issued for corn varieties as support, and argues that any one of these corn plants could be used to produce an F1 hybrid plant having I501150 as one parent, and each of these would share the genetic complement of I501150 (response, page 15, 1st full paragraph and the paragraph bridging pages 15-16).

However, again, it is the interaction of the products of all of the alleles of the claimed hybrids, not just the products of the alleles inherited from I501150, which determine the traits of the claimed hybrids. Each parent contributes one set of chromosomes to the hybrid progeny, and each set of chromosomes comprises one allele for each gene at every locus in the genome, wherein alleles are alternate forms of the same gene that occur at a given locus. A phenotypic trait of the plant results from the expression of the two sets of alleles. The resulting phenotype of the plant depends on how each allelic product interacts with the corresponding allelic product inherited from the other genome, as well as how each gene product interacts with other gene products in the genome. Some alleles of the same gene are dominant to others. The interaction

of nonallelic genes by epistasis also affects the phenotype, and quantitative traits are determined by the combined effects of multiple genes. Given that a claimed hybrid corn plant comprises a set of alleles inherited from each parent and these two sets of alleles interact in a variety of ways to determine the hybrid's morphological and physiological traits, one cannot correlate the alleles inherited from I501150 alone, with the phenotype of the hybrid progeny. Thus, the deposit of I501150 seeds and the recitation of some phenotypic characteristics of corn plant I501150 is not sufficient to provide an adequate written description of all hybrid progeny that may be produced by crossing I501150 with a second, distinct corn plant.

Applicant then returns to the genetic marker data, alleging that the Action attempts to downplay the significance of the genetic marker data in the specification, that no effort was made to show that any substantial numbers of marker loci actually are shared by other plants (response, page 16, 1st full paragraph). However, the specification shows that at least two other inbred corn plants, I754206 and I649539, share many of the same SSR loci (see Table 5). Further, the specification does not mention anything concerning the traits expressed by the I754206 and I649539 plants, and how similar those traits are to the combination of traits expressed by I501150. Furthermore, is a comparison to only two inbreds sufficient to establish that the set of SSR and isozyme markers in Tables 5 and 6 can distinguish plants as having I501150 as a parent from those that do not? Given that I754206 and I649539 share many of the SSR markers possessed by I501150, is the number of markers statistically significant to distinguish this genome from all other genomes? Even if the number of markers is sufficient, the specification fails to correlate any function, or trait, expressed by I501150, or the claimed hybrids, with any of the markers.

Applicant argues, regarding the availability of genetic markers or the primers used to detect the markers, that the service used to detect SSR markers is commercially available to the public, that SSR and other genetic marker systems that are well known may potentially be used, as described in the specification on pages 54-56 (response, page 16, 1st full paragraph). However, that the service used to detect SSR markers is currently commercially available is not a guarantee that it will remain so for the life of a patent issuing from the application. Further, the specification at pages 54-56 only provides a general discussion of other types of genetic markers, and does not describe any actual markers possessed by corn plant I501150.

Applicant next argues, in response to the Examiner's previous arguments that the morphological and physiological characteristics of the hybrids have not been described, and that the manner in which the genes inherited by the hybrids would be expressed or interact has not been shown, that the Examiner's position misses the point that Applicant has gone one step further by describing the claimed hybrid plants at the genetic level. Applicant asserts that a better description could not be made than at the genetic level (response, page 17, 1st full paragraph). However, again, Applicant is attempting to describe the claimed hybrids by only half of their genome. Applicant has deposited I501150 seed and, by extension, the I501150 genome, since the cells of the I501150 seed contain the I501150 genome. The claimed hybrids inherit only half of this genome, and the claimed hybrids do not have all of the same functions as those possessed by I501150. Given the genetic composition at each locus of the second inbred chosen as the hybrid's parent, the resultant hybrid may even have fewer than one-half of the traits exhibited by I501150.

The specification also provides the locus of many SSR and isozyme markers in the genome of I501150. However, as discussed above, the specification does not correlate any function of the claimed hybrids with this genetic information. The specification does not correlate any traits with any genes or molecular markers of I501150, and therefore the claimed hybrids. Further, while I501150 seed has been deposited, none of the hybrid seeds, which produce plants having traits and functions that are different from I501150, have been deposited.

Applicant continues, arguing that the law makes no distinctions regarding the manner in which an applicant chooses to describe claimed compositions (response, page 17, 2nd full paragraph). However, the Examiner has not limited Applicant to describing the claimed composition in any specific manner. Applicant argues that the genetic complement of parent plant I501150 that will be comprised in the claimed hybrid plants has been described by way of the SSR and isozyme genetic marker profiles in Tables 6-9. However, as discussed above, while loci where these markers are located are identified, the sequences of the markers, or of primers used to locate them, are not described, nor are any functions of any alleles that may be associated with the markers described.

Applicant repeats the argument that a further description of the claimed hybrid plants is provided in the specification by way of hybrid 9903904, and believes that this plant is representative of hybrids produced using I501150 as one parent, each of which comprise the genetic complement of the parent corn plant. Applicant argues that the information of Table 4 combined with the SSR and isozyme marker profiles in Tables 7 and 8, and the description of I501150 and the shared structure among the hybrids is more than adequate to describe the claimed subject matter (response, page 18, 1st full paragraph). However, again, hybrids that do

not share both of the same parents will not have the same traits. The morphological traits and performance of hybrid 9903904 cannot be extended to any other hybrid plant that does not have both of the same parents, and are not representative of all hybrids produced using I501150 as one parent.

Regarding claims 27-30, drawn towards corn plant I501150 containing single locus conversions: Applicant appears to be arguing that the specification describes such plants, simply because the definition of "single locus converted plants" provided in the specification indicates that such plants possess essentially all of the desired morphological and physiological characteristics of plant I501150 in addition to the characteristics conferred by the single locus transferred. Applicant argues that because the specification indicates that the claimed plants possess "essentially all of the desired morphological and physiological characteristics of [the single gene converted plant]", that they have more than adequately described such plants (response, paragraph bridging pages 18-19). However, the specification does not describe all single locus conversion traits, nor the source of all of said traits. The traits conferred by the single locus may also change one or more of the traits expressed by I501150, depending on what the locus encodes. A single locus whose product confers male sterility, for example, will change a trait of inbred corn plant I501150, rather than adding an additional trait. Further, the descriptions of plants that express "essentially" all of the "desired" characteristics of I501150 are not described. The definition indicates that the plants possess the "desired" characteristics of I501150. The "desired," as opposed to the "undesired," traits are not described.

Applicant cites *In re Gosteli* for indicating that the written description requirement does not require an applicant to describe exactly the subject matter claimed, but that the description

must clearly allow persons of ordinary skill in the art to recognize what is claimed (response, paragraph bridging pages 18-19). However, the specification does not describe the traits expressed by all of the claimed plants, nor what set of traits are present in all of the claimed plants to allow persons of ordinary skill in the art to recognize the claimed plants. The claimed genus reads on a multitude of I501150 plants further comprising an additional single locus, and having a multitude of different morphological and/or physiological traits. As discussed, the specification does not describe plants that express only some or "desired" traits that are expressed by I501150, or how to distinguish such plants from I501150. Further, single loci, for example those encoding a transcription factor, may affect one or more traits expressed by I501150. The claimed plant then may not express all of the "desired" traits of I501150. Such plants are not described by the specification.

In response to the issue raised in the previous Office actions that the claimed plants encompass introducing genes, or single loci, that have yet to be discovered, Applicant argues that undiscovered genes are not claimed, and that the fact that a given gene could be isolated in the future and introduced as a single locus conversion is irrelevant, because it is the single locus conversion of corn plant I501150 that is claimed (response, paragraph bridging pages 19-20). However, if a gene has not been discovered or isolated at the time the instant application was filed, Applicant cannot be in possession of a corn plant into which this gene was deliberately introduced. Furthermore, at least claim 30 explicitly recites undiscovered genes, since single genes that alone govern "yield enhancement" or "enhanced yield stability" have not been discovered.

Applicant continues, arguing that under the Examiner's reasoning, any claim could be read to encompass subject matter yet to be invented and therefore not described. For example, a corn plant transformed with a particular gene would be invalid because it would encompass corn varieties yet to be discovered (response, paragraph bridging pages 19-20). In this example, however, there is only one genetic structure that is relevant, that of the particular gene, and only one function, that of the product of the gene. A claim drawn towards a corn plant containing the gene may be described, if the structure and function of the gene is described. The corn plant comprising that gene has the function conferred by the encoded gene product. In the instant application, the invention encompasses corn seed I501150 and the plant produced by it. The deposit of the seed satisfies the written description requirement for the I501150 seed, and the functions of the plant are described in Tables 1-3. Another locus that is introduced into I501150 would amend its structure and functions.

Applicant argues that the evidence was submitted in a prior response that shows that the specification recites numerous single locus traits. Applicant goes on to provide several examples (response, pages 20, 1st full paragraph to page to page 22, 1st full paragraph). However, while the specification does cite references that describe numerous isolated genes, not all of the cited references actually teach that certain genes have been discovered or isolated. For example, the references cited in the specification do not describe isolated single genes or loci that confer yield enhancement or yield stability. If such single loci have not been discovered or isolated, Applicant cannot be in possession of I501150 plants comprising this single locus conversion. The claims broadly encompass plant I501150 further comprising any single locus conversion, controlling any trait, including loci that have yet to be identified as independently controlling a

trait. Applicant cannot be in possession of plants further comprising single loci that have yet to be identified. It is also noted that the Examiner is not asking Applicant to identify each and every gene known to man by name, but to identify the types of single loci, that alone control a trait, that have been identified. For example, many genes or single loci were known in the prior art that confer disease resistance, or herbicide resistance.

Applicant argues that techniques for introducing single locus traits by genetic transformation were well known (response, page 23, 1st full paragraph). That methods to produce genetically transformed corn plants existed at the time of the invention is, of course, not disputed. However, methods for producing a product do not describe the product itself.

Regarding claim 31, Applicant argues that the claim is a process claim that involves crossing corn variety I501150 according to the specified steps. Applicant indicates that it is believed that the rejection was made on the position that each product made at any intermediate or penultimate step of the method must be described as if claimed *per se*. Applicant submits that this is a misstatement of the law. Applicant argues that a process is claimed, not a product of a process, and thus the steps of the process must be described, not the intermediate or final products. Applicant argues the starting materials must also be provided, with are plant I501150 and any second corn plant. Applicant argues that the starting material for any step within the method are 1) corn plant I501150, 2) any second corn plant, or 3) a corn plant that is produced by following a preceding step (response, paragraph bridging pages 23-24 and pages 24-25).

The Federal Register (64 Fed. Reg. 71427, 71428 (1999), comment No. 4) contains a suggestion that the Written Description Guidelines should distinguish between claims to processes whose patentability depends on the compositions used in them, as opposed to those

whose patentability rests in the steps of the process itself, and indicates that this suggestion was adopted. Claim 31 includes steps in which hybrids, produced by crossing inbred corn plant I501150 with a second, different corn plant, are involved in crosses as well. The patentability of the method of claim 31 does not lie in the method steps, which require the simple acts of crossing corn plants, allowing seed to be produced, and growing progeny plants from the seed, but rather in the compositions used in the method. The method of claim 31 is not described, as the specification does not sufficiently describe the progeny plants, for the reasons discussed above, which are used in the method. Applicant cites *Vas-Cath, Inc. v. Mahurkar* in support of the argument that all that needs to be shown is that an applicant be in possession of the claimed invention (response, paragraph bridging pages 23-24). However, for the reasons discussed above regarding hybrids produced by crossing corn plant I501150 with a different corn plant, Applicant is not in possession of progeny plants produced in step (a)-(d) of claim 31. Also note that steps (c)-(d) of claim 31 requires possession of plants beyond the F1 generation of plants. Steps (b)-(d) indicate that progeny plants of any generation can be crossed with itself or a second plant. Note that such progeny plants cannot be identified using the genetic markers of I501150 plants in Tables 5 and 6 (even if those markers were fully described), since they would not retain the same combination of markers. The genetic markers in the F1 generation plants are not in homozygous form and presumably are in segregating loci, and so F2 generation plants would not inherit the entire combination of markers. Also note that steps (c) and (d) of claim 31 do not require that the F1 progeny plants, and progeny plants of all subsequent generations, be selfed.

Applicant argues that corn breeding is well known to those of skill in the art, that without it there would not be commercial corn varieties (response, page 23, 2nd full paragraph).

However, it is not disputed that corn breeding is well known. Applicant argues that all of the steps of claim 31 are typical of the process used for the production of new corn varieties, save for the novelty of corn variety I501150 (response, page 25, 2nd full paragraph). The Examiner disagrees, and maintains that the progeny plants of steps (b)-(d) also need to be described, as written description of this process claim depends on compositions used in them, and not in the steps themselves.

6. Claims 27-30 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record stated in the Office action mailed July 9, 2003. Applicant traverses the rejection in the paper filed October 9, 2003. Applicant's arguments have been fully considered but were not found persuasive.

Applicant argues that no basis has been given to show that these references have any relevance to corn plants. Applicant argues that no basis was given to show that the cited references concerning petunias, sugar beets, and tomatoes would apply to corn, and that the Action attempts to require Applicant to show why this is not true. Applicant argues that it is the burden of the Office to support its rejections (response, paragraph bridging pages 25-26 and the paragraph bridging pages 26-27).

However, the rejection was supported with cited references. The rejection raises the issue of how linkage drag hampers the insertion of single genes alone into a plant by

backcrossing, while recovering all of the original plant's genome. Linkage drag appears to be a phenomenon that occurs in all plant types. Examples are lacking in the prior art of plants in which linkage drag does not occur. There is no evidence that corn is exempt from this universal trend. Linkage drag, for reasons discussed in the previous Office action, would prevent one skilled in the art from making the I501150 plants comprising single locus conversions as currently claimed.

Further, the single locus may encode any product having any function, and can therefore affect the other traits expressed by I501150. For example, if the single locus encodes a transcription factor, the expression of numerous genes may be affected, which in turn would affect the traits expressed by I501150. In such a scenario, one may not obtain a plant having all or even most of the desired morphological and physiological traits of I501150, in addition to the trait conferred by the single locus.

In order to produce a single locus converted plant, a first inbred of interest is crossed with another "donor" inbred parent plant, which contains the trait that is to be introduced into the first inbred. The progeny of that cross is then backcrossed with the first inbred. The progeny of the backcross gets backcrossed with the first inbred several more times, until a plant is recovered that has essentially all of the desired morphological and physiological traits of the original, first inbred in addition to the trait (single locus) transferred from the donor inbred parent (specification, paragraph bridging pages 28-29). The claims, however, broadly encompass plants that comprise exactly the genome of I501150, further comprising just a single additional locus. While the introduction of a desired trait from one plant into another using crossing techniques is well known in the prior art, what is not clear is that a plant that has exactly the same genome as

I501150 is recovered, in addition to the introduced single locus. The claims encompass such plants. The very first cross involves crossing I501150 to another plant and results in a plant that expresses traits that are very different from those expressed by I501150, due to the presence of the genetic material from the non-I501150 plant. It is not clear, despite repeated backcrossing with I501150, that a plant having the exact same genome of I501150 can be recovered (in addition to the introduced single locus), particularly in view of the genetic linkage of multiple genes conferring multiple additional traits, as established by the cited references. The specification attempts to address this by indicating that "essentially" all of the "desired" morphological and physiological traits of an inbred are recovered, in addition to the transferred single locus (paragraph bridging pages 28-29). However, the claims are directed to exactly plant I501150 further comprising the single locus.

Proposed Amendments

7. Presented below are proposed new claims that address the subject matter of, and would replace, pending claims 16 and 27-30, which are drawn towards I501150 plants further comprising a nuclear or cytoplasmic gene conferring male sterility, or I501150 plants further comprising a single locus conversion, or wherein the single locus was stably inserted into a corn genome by transformation. Regarding the proposed claims 32-41, directed towards methods comprising transforming a corn plant: the method is considered acceptable to the Examiner because it indicates the traits that would be affected by the transgene (a single locus), or it recites the type of transgene that is intended to be introduced into the plant. Applicant of course would not be limited to only those traits mentioned in the proposed claims. Any trait may be recited,

provided that there is written descriptive support in the specification and the prior art teaches that genes or single loci that affect such traits have been isolated. It is noted that the Examiner is not requiring that the claims recite the actual names of any genes. Regarding proposed claims 42-46, drawn towards a method of introducing a desired trait into the inbred plant of the invention using backcrossing techniques (which would result in plants comprising a single locus conversion, to use the terminology of the instant application): the proposed method claims are considered acceptable because they 1) indicate the type of trait that is contemplated, and 2) indicate that, after the inbred plant of the invention is crossed with a plant that contains the desired trait to be transferred, the progeny plant is to be backcrossed and selected at least four times, to ensure that undesirable genetic material from the donor plant is lost and that the resultant plant will also recover all of the traits of the original plant that are taught in Table 3 of the specification. It is important that the resultant plant retain the traits recited in Table 3, as it is this combination of traits that make inbred corn plant I501150 novel and described. Note that the proposed method claim does not require the recovery of I501150 traits that are absent from Table 3. The method of the proposed claim results in a plant having the traits of I501150 recited in Table 3, in addition to that of the introduced locus.

Proposed Claim Amendments

32. A method of producing a male sterile corn plant comprising transforming the corn plant of claim 5 with a nucleic acid molecule that confers male sterility.

33. A male sterile corn plant produced by the method of claim 32.

34. A method of producing an herbicide resistant corn plant comprising transforming the corn plant of claim 5 with a transgene that confers herbicide resistance.

35. An herbicide resistant corn plant produced by the method of claim 34.

36. The corn plant of claim 35, wherein the transgene confers resistance to an herbicide selected from the group consisting of glyphosate, sulfonylurea, and phosphinothricin.

37. A method of producing an insect resistant corn plant comprising transforming the corn plant of claim 5 with a transgene that confers insect resistance.

38. An insect resistant corn plant produced by the method of claim 37.

39. The corn plant of claim 38, wherein the transgene encodes a *Bacillus thuringiensis* Bt toxin.

40. A method of producing a disease resistant corn plant comprising transforming the corn plant of claim 5 with a transgene that confers disease resistance.

41. A disease resistant corn plant produced by the method of claim 40.

42. A method of introducing a desired trait into corn inbred line I501150 comprising:

(a) crossing I501150 plants grown from I501150 seed, representative seed of which has been deposited under ATCC Accession No. PTA-4489, with plants of another corn line that comprise a desired trait to produce F1 progeny plants, wherein the desired trait is selected from the group consisting of male sterility, herbicide resistance, insect resistance, and disease resistance;

(b) selecting F1 progeny plants that have the desired trait to produce selected F1 progeny plants;

(c) crossing the selected progeny plants with the I501150 plants to produce backcross progeny plants;

(d) selecting for backcross progeny plants that have the desired trait and traits of corn inbred line I501150 listed in Table 3 to produce selected backcross progeny plants; and

(e) repeating steps (c) and (d) three or more times in succession to produce selected fourth or higher backcross progeny plants that comprise the desired trait and all of the traits of corn inbred line I501150 listed in Table 3 as determined at the 5% significance level when grown in the same environmental conditions.

43. A plant produced by the method of claim 42, wherein the plant has the desired trait and all of the traits of corn inbred line I501150 listed in Table 3 as determined at the 5% significance level when grown in the same environmental conditions.

44. The plant of claim 43 wherein the desired trait is herbicide resistance and the resistance is conferred to an herbicide selected from the group consisting of: sulfonylurea, glyphosate, and phosphinothricin.

45. The plant of claim 43 wherein the desired trait is insect resistance and the insect resistance is conferred by a transgene encoding a *Bacillus thuringiensis* Bt toxin.

46. The plant of claim 43 wherein the desired trait is male sterility and the trait is conferred by a nucleic acid that confers male sterility.

Summary

8. Claims 1, 5, 7-10, 12, 13, 15, and 17-23 are allowed. Claims 2, 3, 6, 11, 14, 16, 24, 25, and 27-31 remain rejected.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

January 12, 2004

Ashwin D. Mehta, Ph.D.
Primary Examiner
Art Unit 1638